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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,310	10/01/2001	Antonio Nanci	104/50108	8938

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	8

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,310	NANCI ET AL.	
	Examiner	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-14 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the claimed rodent model differs from the in vivo rat model described by McKee and Warshawsky, therefore, the claimed invention provides a special technical feature that makes a contribution over the prior art. Consequently, the inventions of Groups I-VIII are closely connected by a common special technical feature, and search and examination of all the claims can be made without serious burden.

This is found partially persuasive. The Examiner acknowledges that the in vivo rat model described by McKee and Warshawsky differs from the claimed invention. As such, the invention of Group I and II will be combined. However, the special technical features of Groups III-VIII differ from the special technical feature of Groups I and II. For example, the special technical feature of Groups I is a rodent model. The special technical feature of Group II is the drug screen and the rodent model. Then the inventions of Groups I and II share a common special technical feature. The special technical feature of Group III is the rodent model and the histological and histomorphometric parameters of the alveolar bone. The special technical feature of Group III thus differs from the special technical feature of Group II. Similarly, the special technical feature of Group IV is the rodent model and immune response elicited by the pathogen; the special technical feature of Group V is the rodent model and toxicity of a biomaterial components; the special technical feature of Group VI is the rodent model and the genetic material transfer; the special technical feature of Group VII is the rodent model and the

gene expression construct that inducing or repressing expression of a gene product; the special technical feature of Group VIII is a non-human mammal in situ knock-out model. The special technical features of Groups III-VIII are different from each other. In addition, they are different from the special technical feature of Group II. Therefore, they do not form a single general inventive concept under PCT Rule 13.1.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 9-14 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-8 are currently under examination.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

The Nature of the Invention:

The nature of the invention is a method for screening drugs for a potential bone disease therapy compound or a compound inducing tissue repair by administering said compound to a rodent model comprising a mandibular incisor and a window in an alveolar bone overlying the incisor's apex or along radicular surface; and determining histological and histomorphometric parameters of alveolar bone, wherein an increase in anabolic activity or a decrease in catabolic activity are indicative of a bone disease therapy compound or a compound inducing tissue repair.

The Breadth of the Claim:

The breadth of the claim encompasses a method for screening drugs for any type of bone disease. It further encompasses a drug screening method wherein the drug is administered to the rodent model by any routes including oral, topical, intramuscular, or systemic administration.

The amount of Guidance Provided in the Specification:

The teaching of the specification relative to the claimed scope is limited. The specification teaches a rat model that comprises a mandibular incisor and a window in an alveolar bone overlying the incisor's apex or along radicular surface, and administering compound through this window result in selective delivery of said compound to the odontogenic organ which affects the eruption of the incisor. The specification fails teach a drug screen method by delivering the compound to the rat model by any other routes. Further, the specification fails to teach what kind of histological and histomorphmetric parameters that indicate an increase in anabolic activity or decrease in catabolic activity in the alveolar bone that would indicate potential bone disease therapy or tissue repair. Therefore, the scope of the claim surpasses the teaching of the specification.

The state of prior art:

The state of art at the time of filing is silent on using the rat model for screening drugs that induces tissue repair or potential bone disease therapy compound, wherein the histological and histomorphmetric parameters that indicates an increase in anabolic activity or a decrease in catabolic activity in alveolar bone determines the effectiveness of the drug. As such, the skilled artisan would have to rely on the guidance of the specification to practice the method as claimed.

However, as discussed above, the specification does not teach what types of histological or histomorphmetric parameters that indicate increase in anabolic activity or decrease in

catabolic activity in alveolar bone that would determine the effectiveness of the drug for inducing all types of tissue repair or treating all types of bone disease such as osteoporosis. In addition, the specification fails to teach whether delivering the drug to the rat model by any other routes (not through the window) would affect odontogenic tissue and eruption of the incisor. Therefore, without teaching from the specification, one skilled in the art would have to engage in undue experimentation to practice the method as claimed.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for screening for a potential anti-cancer therapy compound by administering the compound locally through the window of the rodent model, does not reasonably provide enablement for claimed method wherein the compound is administered by any other method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

See reasons discussed above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "a growth factor or a combination thereof" renders the claim indefinite because it is unclear what the combination encompasses. As such, the metes and bounds of the claim cannot be established.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouhayoun et al (1992, Journal of Material Science: Materials in Medicine, Vol 3, p222-228).

Ouhayoun et al. teach a swine model that comprising a mandibular incisor and a window in an alveolar bone adjacent to the incisor and below the alveolar crest. However, Ouhayoun et al. do not teach a rodent model as claimed.

It would have been obvious to one of ordinary skill of art to make a rodent model comprising a mandibular incisor and window in the alveolar bone adjacent to the incisor and below the alveolar crest because the teaching of Ouhayoun et al. Use of rodent model such as rat is common practice because it is smaller than swine, easier to for experimental manipulation, and more cost effective. Since Ouhayoun et al. have already taught a swine model comprising a mandibular incisor and a window in an alveolar bone adjacent to the incisor and below the alveolar crest, and how to make such a model, one of ordinary skill in the art would have reasonable expectation of success to apply the same method to a rodent and making a rodent model comprising a mandibular incisor and window in the alveolar bone adjacent to the incisor and below the alveolar crest. Therefore, the invention would have been *prima facie* obvious for one of ordinary skill of art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER